

**REMARKS**

Applicants respectfully request reconsideration and reexamination of the present application in light of the amendments and the remarks below.

Claims 1-7 and 9-12 are pending in this application. Claims 7 and 9-11 have been amended and claim 12 has been added. These claim amendments and additions are made to clarify the subject matter therein. Therefore, these amendments are submitted in order to place the claims in condition for allowance, and do not disclaim any subject matter to which the Applicants are entitled.

***Rejection Under 35 U.S.C. § 112, second paragraph***

The Examiner rejected claims 9 and 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention (Paper No. 6, pages 7-8). Applicants respectfully traverse this rejection.

The Examiner stated:

Claim 9 is drawn to medicaments. However, it is unclear what subject matter Applicant intends to claim through the use of the term. It is suggested that Applicant delete "medicament" and insert -composition- in order to obviate the rejection under 112 second paragraph.

Claim 10 contains the term "and/or" which renders the claim indefinite. It is not clear whether claim 10 is drawn to methods of treating both states of pain and neurodegenerative disorders, or whether the claim is drawn to treating only one of the conditions.

Claims 9 and 10 have been amended to clarify the claimed subject matter. Specifically, claim 9 has been amended as suggested by the Examiner. Claim 10 has been amended to recite a method of treating pain, and claim 12, directed to a method of treating neurodegenerative disorders, has been added.

It is thus submitted that the claims 9 and 10 meet the requirements of 35 USC § 112, second paragraph, and reconsideration and withdrawal of the present rejection is respectfully requested.

***Rejection Under 35 U.S.C. § 112, first paragraph***

The Examiner rejected claims 10 and 11 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (Paper No. 6, pages 5-7).

The Examiner stated:

Claims 10 and 11 are directed to "a method of ...preventing states of pain and/or neurodegenerative disorders" and a method of...preventing Parkinson's disease". The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are a vast number of neurodegenerative disorders, including Parkinson's disease, and Applicant does not give support for "preventing" all forms neurodegenerative disorders. The art pertaining to neurodegenerative disorders remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that Applicant delete "preventing" from claims 10 and 11 and that in claim 10, Applicant incorporate into claim 10, the states of pain and neurodegenerative disorders that are supported in the specification, e.g., on pages 16-18, in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

Claims 10 and 11 have been amended to clarify the claimed subject matter. Specifically, claims 10 and 11 have been amended as suggested by the Examiner.

It is thus submitted that the claims 10 and 11 meet the requirements of 35 USC § 112, first paragraph, and reconsideration and withdrawal of the present rejection is respectfully requested.

#### ***Rejection Under 35 U.S.C. § 102***

On page 2 of Paper No. 6, the Examiner rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by STN International CAPLUS Database, Accession No. 1991:514130; Fujisawa Pharmaceutical Co., Ltd, Japanese Patent JP03056431 (1991), abstract ("JP03056431").

In order to support anticipation under 35 U.S.C. § 102, each and every element of a claimed invention must be disclosed within a single prior art reference. *See In re Bond*, 15 USPQ2d 1896 (Fed. Cir. 1991).

The present invention relates to phenoxyphenylalkanesulphonates and methods of treating pain and neurodegenerative disease by administration of the compounds of the present invention.

The compounds disclosed in JP03056431 are biphenyl compounds. In particular, Formula (I) requires that each phenyl ring must be substituted in the 4-position with R<sup>1</sup> and R<sup>2</sup>, respectively. However, the compounds of the present invention may be substituted at any available carbon on the phenyl ring. That is, for the compounds of the present invention, R<sup>1</sup>, R<sup>2</sup>, R<sup>4</sup>, and A may be substituted at any position on the phenyl ring, and substitution at the 4-position is not required.

Therefore, since JP03056431 does not teach substitution at any available carbon on the phenyl, JP03056431 does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

***Rejection Under 35 U.S.C. § 103(a)***

On pages 2-5 of Paper No. 6, the Examiner rejected claims 1-5 under U.S.C. § 103(a) as unpatentable over STN International CAPLUS Database, Accession No. 1991:514130; Fujisawa Pharmaceutical Co., Ltd, Japanese Patent JP03056431 (1991), abstract ("JP03056431"). Applicants respectfully traverse.

To properly maintain a rejection under 35 U.S.C. § 103, three conditions must be met. First, the prior art must have suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the prior art must also have revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in the Applicant's disclosure. Finally, the prior art reference must teach or suggest all the claim limitations. *See In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

The present invention relates to phenoxyphenylalkanesulphonates and methods of treating pain and neurodegenerative disease by administration of the compounds of the present invention. As discussed above, the compounds disclosed in JP03056431 are biphenyl compounds in which each phenyl ring must be substituted in the 4-position with R<sup>1</sup> or R<sup>2</sup>, respectively. However, JP03056431 does not teach or suggest substitution at any available carbon on the phenyl. As one skilled in the art would appreciate designing a pharmaceutical is an unpredictable science. Thus, it would be readily apparent to one skilled in the art that the position of a substitution on a structure is chemically significant, particularly where functionality of the compound depends on interaction with a specific protein (e.g., receptor). As such, one skilled in the art would not be motivated to prepare the compounds of the present invention with the expectation of producing compounds with biological activity. That is, based on the disclosure of JP03056431, one skilled in art would assume that substitutions at the 4-position on both phenyl rings are critical for biological activity. One would not expect that substitutions could be made at any position on the phenyl ring, and the compound would still possess biological activity. Thus, Applicants do not see where there is a suggestion to make the compounds of the present invention. Even if there were, nothing suggests that if such compounds were made, the resulting compounds would be successful. Thus, one skilled in the art would not have been motivated to prepare the compounds of the present invention with the requisite reasonable expectation of success.

It is therefore respectfully submitted that JP03056431 fail to teach or suggest the compounds as presently claimed, and that the current invention is novel and nonobvious in view of the prior art references. For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the present rejection.

***Claim Objections***

The Examiner objected to claims 3 and 4 as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim (Paper No. 6, page 8).

Claim 3 depends from claim 1 or 2 and claim 4 depends from claim 1 or 2. Claim 2 depends from claim 1, and claim 1 is an independent claim. Thus, neither claim 3 nor claim 4 depends from a multiple dependent claim which depends from another multiple dependent claims. Therefore, Applicants submit that claim 3 and 4 are in proper form.

The Examiner objected to claim 7 because claim 7 is a compound claim which is dependent on a process claim (Paper No. 6, page 8). Claim 7 has been amended accordingly.

It is submitted that Applicants have overcome the claim objections, and thus, claims 3, 4, and 7 are allowable.

***Allowable Subject Matter***

Applicants acknowledge that the Examiner objected to claim 6 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims (Paper No. 6, page 8).

**CONCLUSION**

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections and objections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Wright is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

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Respectfully submitted,

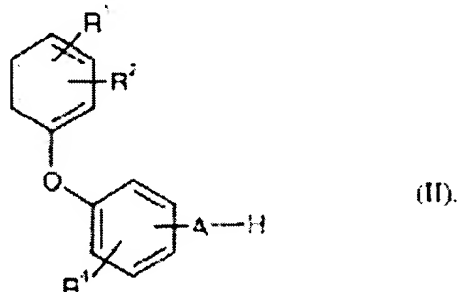
  
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New Claims (Attorney Docket No. LeA 34 813)

- 13
12. (New) A method of treating states of neurodegenerative disorders, comprising administering to a mammal an effective amount of a compound according to claim 1, wherein said neurodegenerative disorder is cerebral vasospasm, cerebral ischaemias, craniocerebral trauma, migraine, spasticity, anoxia, hypoxia, perinatal asphyxia, autoimmune diseases, metabolic diseases, organic diseases, epilepsy, brain disorders associated with atherosclerotic disease or arteriosclerotic disease, depression, Alzheimer's disease, Parkinson's disease, Huntington's disease, multiple sclerosis, amyotrophic lateral sclerosis, multi-infarct dementia, or neurodegenerative disorders associated with bacterial and viral infections.

## Amended Claims (Attorney Docket No. LeA 34 813)

- 13 2
7. (Amended) Compounds of the general formula (II),



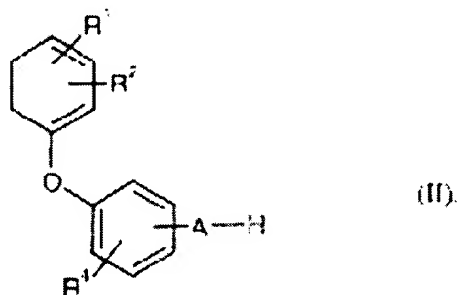
in which  $R^1$ ,  $R^2$ ,  $R^4$  and A have the meaning stated in Claim 1.

- 13 2
9. (Twice amended) A pharmaceutical composition containing at least one of the compounds according to Claim 1 mixed with at least one pharmaceutically suitable essentially nontoxic carrier or excipient.
10. (Twice amended) A method of treating states of pain, comprising administering to a mammal an effective amount of a compound according to claim 1, wherein said pain is acute pain, chronic pain, cancer-induced pain, chronic neuropathic pain, diabetic neuropathy, neuralgia, peripheral nerve damage, central pain, trigeminal neuralgia, lumbago, back pain, or rheumatic pain.
11. (Twice amended) A method of treating Parkinson's disease, comprising administering to a mammal an effective amount of a compound according to claim 1.

Amendments to the Claims (Attorney Docket No. LeA 34 813)  
Version with Markings to Show Changes to Specification

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7. (Amended) Compounds of the general formula (II), [according to Claim 6]



in which R<sup>1</sup>, R<sup>2</sup>, R<sup>4</sup> and A have the meaning stated in Claim 1.

9. (Twice amended) [Medicaments] A pharmaceutical composition containing at least one of the compounds according to Claim 1 mixed with at least one pharmaceutically suitable essentially nontoxic carrier or excipient.
10. (Twice amended) A method of treating [or preventing] states of pain [and/or neurodegenerative disorders], comprising administering to a mammal an effective amount of a compound according to claim 1, wherein said pain is acute pain, chronic pain, cancer-induced pain, chronic neuropathic pain, diabetic neuropathy, neuralgia, peripheral nerve damage, central pain, trigeminal neuralgia, lumbago, back pain, or rheumatic pain.
11. (Twice amended) A method of treating [or preventing] Parkinson's disease, comprising administering to a mammal an effective amount of a compound according to claim 1.